

REMARKS

Claim rejections – 35 U.S.C. §112, first paragraph (written description)

Claims 1, 3, 4, 15-17, 19, 20, 23-31, and 58 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. This rejection is based on the fact that the scope of the claims include genomic DNA encoding SEQ. ID. NO: 2. The Office Action states that the limitation "genomic DNA" in claim 4 indicates that the scope of claim 1 includes genomic DNA encoding SEQ. ID. NO: 2. Applicants have amended claim 4 to remove the phrase "genomic DNA."

Claim rejections – 35 U.S.C. §112, first paragraph (enablement)

Claims 1-4, 15-17, 19-20, 23-31, and 58 are rejected under U.S.C. §112, first paragraph, for failing to comply with the enablement requirement. The Office Action states that the claimed invention is drawn to SEQ. ID. NO: 1 for use in detection of megakaryocytic abnormality, and cites Applicants' previous response to the Restriction Requirement as support for this statement. Applicants note that the species election made in response to the Restriction Requirement did not limit the invention to SEQ. ID. NO: 1. Rather, the species election was drawn to a nucleic acid encoding the first splicing variant of SH3D1A, i.e., SEQ. ID. NO: 2. Thus, the claimed invention is drawn to nucleic acids encoding SEQ. ID. NO: 2, not just the nucleic acid set forth in SEQ. ID. NO: 1.

The Office Action goes on to reject Applicants' previous argument that the use of the sequences of the invention is not limited to detecting megakaryocytic abnormalities

by measuring SH3D1A expression. The Office Action bases this rejection on the fact that claim 58 is still drawn to the isolated nucleic acid of claim 1 wherein said nucleic acid is used to detect megakaryocytic abnormality. According to the Office Action, one of skill in the art would have reason to doubt familial platelet disorder (FPD) or any other megakaryocytic abnormality could be detected by the claimed nucleic acids due to a post-filing date publication (Song et al.) which teaches that FPD is caused by mutations in CDFA2, not SH3D1A.

Applicants have canceled claim 58, and asserts that this is sufficient to overcome this rejection. As discussed in the previous Amendment and Response, the nucleic acids of the invention may be used, for example, to diagnose clinical features associated with Down Syndrome, based on the localization of the SH3D1A gene to the 21q22 region of chromosome 21.

Claim rejections – 35 U.S.C. §102(b)

Claims 1, 3, 4, 17, 23-29, and 58 are rejected under 35 U.S.C. §102(b) as anticipated by Chen and Antonarakis. The Office Action states that Chen and Antonarakis teach two YAC clones of 838C7 and 860G11 between markers D21S319 and D21S65, the isolated genomic DNA from these two YAC clones, and several other cosmids that all appear to contain the SH3D1A gene located between markers D21S319 and D21S65. According to the Office Action, the YACs and cosmids being amplified using SH3D1A specific primers as shown in Figure 1 all appear to contain genomic DNA encoding the present SEQ. ID. NO: 2. The Office Action goes on to state that the burden is on the Applicants to prove that the nucleic acids contained in YAC

clones 838C7 and 860G11 do not possess the same structural characteristics as the nucleic acids of the present invention.

A claim is anticipated only if each and every element of the claim is found, either expressly or inherently, in a single prior art reference (M.P.E.P. 2131). When a claim covers several compositions (i.e., a set of nucleic acids encoding the polypeptide of SEQ. ID. NO: 2), it is anticipated if any of the compositions within the scope of the claim are disclosed in the prior art (M.P.E.P. 2131). Chen and Antonarakis do not disclose a single isolated nucleic acid sequence, much less an isolated nucleic acid sequence encoding the polypeptide of SEQ. ID. NO: 2. Absent such a disclosure, Chen and Antonarakis do not anticipate the present invention, because they do not disclose every element of the claims.

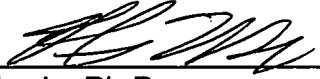
CONCLUSION

In view of the foregoing, it is submitted that the present claims are in condition for allowance. Accordingly, Applicants respectfully request that a Notice of Allowance be issued.

Respectfully submitted,
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Date: _____

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